JUDGE TORRES

13 CIV 4360

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HIKMA PHARMACEUTICALS LLC,

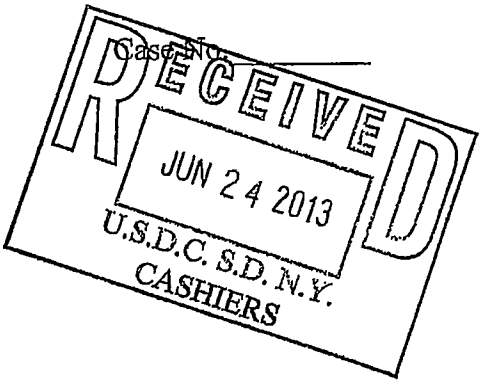
Plaintiff,

v.

EAGLE PHARMACEUTICALS, INC.,

Defendant.

Case No.



COMPLAINT

Hikma Pharmaceuticals LLC ("Hikma" or "Plaintiff"), by and through its undersigned attorneys, and for its complaint against Eagle Pharmaceuticals, Inc. ("Eagle" or "Defendant") alleges as follows:

SUMMARY OF THE COMPLAINT

1) This Complaint involves a generic drug developed by Eagle that is currently pending for approval at the United States Food and Drug Administration ("FDA"). Eagle sold its rights to the drug including an associated Abbreviated New Drug Application ("ANDA" or "Application") to Hikma for $3.5 million in a March 28, 2012, Asset Purchase Agreement ("APA"), but retains responsibility over the Application until the drug is approved.

2) On May 31, 2013, Eagle failed to obtain approval of the Application within the time period prescribed by the APA, and Hikma terminated the APA in accordance with its terms. Hikma also tendered its rights in the drug to Eagle and demanded a refund of the purchase price. Eagle has refused to repay Hikma and breached the APA. (Count I *infra* at ¶s 29-36).

3) The original ANDA filed by Eagle failed to disclose serious manufacturing problems in making the drug. Defect rates exceeding 90% affect this product. These facts were

material to the ANDA and Eagle knew that it should have disclosed them to FDA. When Hikma became aware of the problems earlier this year it demanded that Eagle bring them to FDA's attention but Eagle refused.

4) Hikma did not know about the defects when it signed the APA. Eagle prevented Hikma from learning about them by cherry-picking samples of the drug for Hikma's inspection and representing that a copy of the ANDA it provided Hikma was truthful and complete, knowing that material information was missing from the Application and that such omission would deceive Hikma into believing that the development of the drug was complete. Thus, Eagle has committed fraud in the inducement. (Count II, *infra* at ¶s 37-42). In addition, equitable rescission is appropriate in view of the inability of Eagle to provide quality product under the APA. (Count III, *infra* at ¶s 45-48).

5) Eagle, in early 2013 without any basis, made a demand for adequate assurances that Hikma begin launch preparations under the APA. When Hikma refused to make those launch preparations, Eagle accused Hikma of repudiating the Agreement under New York's Uniform Commercial Code, and informed Hikma that it was relieved of all further obligations under the APA, including any obligation to refund Hikma its $3.5 million. This claim of repudiation is baseless, and Hikma seeks a Declaratory Judgment regarding the disputed contract terms to resolve it. (Count IV, *infra* at ¶s 49-51).

THE PARTIES

6) Plaintiff Hikma Pharmaceuticals LLC is a limited liability corporation duly authorized and validly existing under the laws of the country of Jordan, having a principal place of business in Amman Jordan. Hikma is a manufacturer of generic drugs, and through various

affiliates distributes its drugs in more than 50 countries around the world, including the United States.

7) On information and belief, Defendant Eagle Pharmaceuticals, Inc. is a corporation duly authorized and validly existing under the laws of the State of Delaware, with a principal place of business in Woodcliff Lake, New Jersey.

8) Eagle may be served process upon its registered agent Corporation Service Company at 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808.

JURISDICTION AND VENUE

9) As an action between citizens of a State and citizens or subjects of a foreign state, in a dispute whose amount in controversy exceeds $75,000, this Court is vested with diversity jurisdiction under 28 U.S.C. § 1332(a)(2).

10) This Court has personal jurisdiction over Eagle based on Eagle's voluntary submission to the jurisdiction of this Court in section 9.7 of the APA.

11) Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) and/or (b)(3) based on the parties' agreement to venue in this Court under section 9.7 of the APA, and the negotiation and closing of the APA in the Southern District of New York.

GENERAL ALLEGATIONS

12) Hikma closed the APA with Eagle on March 28, 2012 in New York City, with Eagle expecting FDA approval in the very near future. The sales forecasts for the drug were significant, and the parties met regularly in the following months to plan an efficient and profitable launch.

13) FDA issued a "Quality Deficiency" letter on May 10, 2012 demonstrating "non-approvable" status under the APA. Eagle responded to the letter on May 31, 2012, with the understanding that the FDA would continue the approval process based on that response.

14) During the next twelve months the Application languished at FDA and Eagle revealed to Hikma, for the first time, serious problems with the drug and product defects that Eagle and its third party manufacturer were experiencing.

15) In the latter part of 2012, Hikma worked with Eagle and the drug's manufacturer to solve these problems. Hikma also placed orders for more than $2 million in raw material and finished goods, as a demonstration of its goodwill, based on Eagle's representations that FDA approval was imminent.

16) As Hikma became aware of the product defects, Hikma questioned Eagle about its omission of material information from the Application to FDA. It also asked to see all of Eagle's correspondence with FDA and demanded that Eagle bring the problems with the drug to FDA's attention. Eagle denied Hikma's request to see all of its FDA correspondence.

17) When it became clear to Hikma that Eagle would not inform FDA about these problems, and that it was intent on securing approval from FDA based on an incomplete Application, Hikma canceled its orders for raw material and finished product, and on April 28, 2013, informed Eagle that it intended to terminate the APA as of May 30, 2013, based on Eagle's failure to secure approval within the one year period described in section 2.4.1 of the APA.

18) Eagle issued its own letter on April 17, 2013, demanding adequate assurances that Hikma would perform under the APA. Eagle demanded that Hikma place new orders for inventory in preparation for FDA's approval, and that Hikma affirm its intention to launch the drug once FDA issued its approval.

19) There is nothing in the APA that obligated Hikma to purchase raw materials or finished product in advance of FDA approval. Section 2.2 only requires Hikma to launch the product within 90 days after FDA approval.

20) Eagle demanded adequate assurances as a ruse to complicate Hikma's termination, and to complicate Hikma's efforts to obtain a refund of its $3.5 million.

21) Hikma properly terminated the APA. After Eagle obtained the non-approvable letter on May 10, 2012, Eagle responded to the deficiencies to FDA on May 31, 2012. Under FDA procedures and guidelines, this constituted an FDA agreement to "continue its review" of the application under section 2.4.1 of the APA. At that point in time, Eagle was obligated to secure approval within "twelve months".

22) Eagle did not secure such approval.

23) Accordingly, when Hikma gave Eagle notice of its intention to terminate on April 28, 2013, Hikma fulfilled its obligation to furnish its termination notice "before the 30th day from the end of the twelve month period," and "immediately terminated" the APA on May 31, 2013.

24) Under Section 2.4.2, Hikma tendered the Purchased Assets (as defined in APA) to Eagle, and requested Eagle's return of the purchase price. However, Eagle has so far refused Hikma's tender, and refused to refund Hikma its $3.5 million.

25) When Hikma purchased the rights to market the drug from Eagle on March 28, 2012, it was unaware that the drug suffered from serious quality issues, despite having undertaken a prudent and reasonable diligence review. Hikma visited Eagle's facility in Woodcliff Lake, New Jersey on May 23, 2011, to review the Application and other development documents associated with the drug; traveled to India to audit the drug's manufacturer; and even reviewed samples of the drug furnished by Eagle employees.

26) Hikma did not discover the problems with the drug because Eagle had cherry-picked samples for Hikma to review, hid from Hikma that its FDA Application was incomplete, and hid from Hikma that its development activities were still ongoing.

27) During these investigations, Eagle knew that the drug produced by its manufacturing process would suffer visible quality defects or develop visible defects during the shelf-life of the product. These defects include erosion, chipping, and off-center bulges. However, Eagle had not and still has not disclosed the problems to FDA.

28) On May 14, 2013, when Eagle's contract manufacturer learned that FDA would be inspecting its facility, it sent Eagle the following email asking to destroy samples that could reveal the problems:

> In view of the USFDA audit, we kindly request you to authorize us for destruction of below available samples from PQ1 & PQ2.

COUNT I – BREACH OF CONTRACT

29) Hikma repeats and realleges the allegations of paragraphs 1 through 28 as if fully set forth herein.

30) Section 2.4 the APA states that Hikma can terminate the agreement and obtain a refund of its purchase price under the circumstances recited in Section 2.4.1, reproduced below:

> If ... the FDA communicates to Seller in any manner that the product is "not approvable", Seller will have 120 days to meet with FDA and obtain an agreement from the FDA to continue its review of the Product. ... if the Product is not approved by the FDA within twelve (12) months of obtaining such an agreement from the FDA [to continue its review of the Product], Buyer may, subject to Section 2.4.2, immediately terminate this Agreement by delivering written notice to Seller on or before the 30th day from the end of such ... twelve (12) month period."

31) When FDA issued Eagle a non-approvable letter on May 10, 2012, it communicated that the Application was not approvable within the meaning of section 2.4.1.

32) When Eagle submitted a response to the FDA on May 31, 2012, it secured FDA's agreement to "continue its review" of the application under section 2.4.1 of the APA. At that point in time, Eagle was obligated to secure approval "within twelve months." Id.

33) Hikma's notice of its intention to terminate that issued on April 28, 2013, was "before the 30th day from the end of the twelve (12) month period" and was a proper termination under 2.4.1 of the APA.

34) The APA "immediately terminated" on May 31, 2013.

35) In compliance with section 2.4.2, Hikma tendered the Purchased Assets to Eagle, and requested Eagle's return of the purchase price.

36) Eagle was obligated by the APA to refund Hikma its $3.5 million, and breached its corresponding obligations under section 2.4.1 by failing to refund this amount.

COUNT II – FRAUD

37) Hikma repeats and realleges the allegations of paragraphs 1 through 36 as if fully set forth herein.

38) Bikram Malik, Eagle's Director of Business Development, and Amit Maitra, Eagle's Senior Director of Pharmaceutical Development, furnished samples of the drug to Hikma's Elizabeth Marro and Thomas Vandervort during their May 23, 2011, diligence visit to Eagle, and presented the samples as representative of the drug product, knowing it was not.

39) On information and belief, Eagle was aware that the drug suffered from quality defects when Hikma was performing its diligence, but failed to disclose the defects to Hikma and intentionally hid those defects from Hikma by cherry picking high quality samples for Hikma to review.

40) Having presented the samples as representative, knowing that the defects with the drug were peculiarly within its possession, and knowing that the defects would not otherwise be discovered through Hikma's reasonable care and diligence, Eagle's Bikram Malik and Amit Maitra were under a duty to disclose to Hikma the drug defect problems. Eagle breached this duty.

41) Eagle's Bikram Malik, Amit Maitra, and Christopher Butler, furnished the ANDA to Ms. Marro and Mr. Vandervort during their May 23, 2011, diligence visit as an accurate portrayal of the drug's development and manufacturing status. However, they knew that the ANDA omitted critical development information; specifically the low quality of product produced. Persons involved in the pharmaceutical industry would expect this type of information to be included in the ANDA. Eagle thus knew that Hikma would be misled by the omission of the information even in the exercise of reasonable diligence.

42) Accordingly, when Eagle's Bikram Malik, Amit Maitra, and Christopher Butler furnished the ANDA to Ms. Marro and Mr. Vandervort for their review on May 23, 2011, they did so intending to deceive Hikma regarding the quality of the drug product and the completeness of the manufacturing process.

43) These facts were material to Hikma during its evaluation of the transaction, and were peculiarly within the possession of Eagle. Eagle hid the facts from Hikma intentionally for the purpose of inducing Hikma to enter into the APA, knowing that Hikma would not uncover them during a reasonable and diligent investigation.

44) Hikma justifiably relied on the omissions and affirmative representations when it entered into the APA, and has been injured as a result in the amount of its $3.5 million purchase

price, in addition to profits it would have made if the assets it purchased had been in the condition they were represented, and interest thereon.

COUNT III – RESCISSION

45) Hikma repeats and realleges the allegations of paragraphs 1 through 44 as if fully set forth herein.

46) When Hikma executed the APA and made its $3.5 million payment to Eagle, it was laboring under the incorrect assumption that the manufacturing process for the drug was complete and supported an FDA approval. It was also laboring under the incorrect assumption that the drug did not suffer from material defects.

47) The quality defects in the drug and the deficiencies in the manufacturing process were peculiarly within the knowledge of the Eagle and, given Eagle's deceptive behavior, incapable of discovery by a prudent purchaser exercising due care with respect to the subject transaction. In addition, they materially impair the value of the APA.

48) Accordingly, Eagle's nondisclosure of these material facts constitutes a basis for rescission of the APA as a matter of equity. Hikma has tendered the assets it acquired in the APA to Eagle, and respectfully requests that the APA be rescinded.

COUNT IV – DECLARATORY JUDGMENT

49) Hikma repeats and realleges the allegations of paragraphs 1 through 48 as if fully set forth herein.

50) There is an actual justiciable controversy between the parties regarding the bases for a termination under section 2.4.1 of the APA, whether the APA has in fact been terminated, and whether a refund is owed under section 2.4.2.

51) Under the terms of 28 U.S.C. § 2201, the Federal Declaratory Judgment Statute, Hikma respectfully requests a declaration that the APA was terminated as of May 31, 2013, upon Eagle's failure to secure approval of the Application, and that Eagle owes Hikma its $3.5 million purchase price. Hikma further seeks a declaration that Eagle's claim that Hikma repudiated the APA is baseless.

DEMAND

WHEREFORE, Hikma hereby demands from Eagle:

I. A judgment declaring Eagle in breach of the APA, awarding damages in the amount of $3.5 million plus interest;

II. A judgment that Eagle defrauded Hikma into executing the APA;

III. Compensatory damages in an amount sufficient to make Hikma whole from Eagle's fraudulent behavior, including:

(1) The $3.5 million purchase price paid by Hikma to Eagle under the APA;

(2) Expenses incurred by Hikma for investigating the problems with the drug as they emerged; and

(3) Hikma's lost profits resulting from its inability to enter the market for the drug.

IV. Punitive damages as a consequence of Eagle's fraudulent misrepresentations, in an amount sufficient to deter Eagle from similar future misconduct.

V. Alternatively, rescission of the APA, and a return of the parties to their respective positions before the APA was executed.

VI. A declaration from the Court that Hikma termination of the APA was effective as of May 31, 2013, when Eagle failed to secure FDA approval of the Application, and that Eagle owes Hikma its $3.5 million purchase price;

VII. Reasonable attorney fees Hikma has incurred in connection with this action.

VIII. Prejudgment and post-judgment interest, and all other reasonable costs and expenses incurred prosecuting this action.

IX. Such other relief that this Court deems just and proper.

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